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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/737,687	12/14/2000	Darin Arthur Allen	218	1550

7590 11/19/2003

Axys Pharmaceuticals, Inc.
180 Kimball Way
South San Francisco, CA 94080

EXAMINER

WRIGHT, SONYA N

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/737,687	ALLEN ET AL.	
	Examiner	Art Unit	
	Sonya Wright	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 18-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☒ Claim(s) 1-8 and 10-17 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-31 are pending in this application. In view of the election of Group I in the Paper filed October 15, 2001, claims 9, and 18-31 have been withdrawn for being drawn to non-elected inventions.

Election/Restrictions

Applicants' election with traverse of the species of page found on page 66, line 8 in the paper filed August 29, 2003, is acknowledged. The traversal is on the ground(s) that the P.T.O. does not have the authority to compel an Applicant to divide up her or his generically claimed invention pursuant to an election of species requirement. Applicants argue that the Examiner has intertwined elements of restriction practice with those required to support an improper Markush group rejection. Applicants maintain that restriction practice is distinct from an improper Markush group rejection of a claim due to a lack of unity of invention. Applicants point out the "a reasonable number" of species refers to those specifically enumerated by a claim and not to the number of species embraced by the generic claim in 809.02 (c) of the M.P.E.P. Applicants argue that if the elected species is ultimately found patentable, then examination is extended to the provisionally withdrawn subgenera. Applicants argue that while it is proper to withdraw non-elected subject matter provisionally during an examination of a species, it is improper to withdraw permanently from consideration all non-elected species. Applicants argue that contrary to the Examiner's discussion of "distinct compounds (or species) within each invention" it should be noted that the Applicants consider the Application to contain one invention of which there are different aspects. Applicants

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argue that the Examiner's action of defining what constitutes the Applicants invention is improper. Applicants argue that the Examiner gives no grounds in the August 4, 2003 Office Action upon which to support the claim of serious burden.

However, even though an art rejection has not been made in this application, the requirement for restriction is maintained and the search has not been extended. It is pointed out that the restriction requirement is made under 35 U.S.C. 121. 35 U.S.C. 121 gives the Commissioner (Director) the authority to limit the examination of an application where two or more independent and distinct inventions are claimed to only one invention. The Examiner has indicated that more than one independent and distinct invention is claimed in this application and has restricted (limited) the claimed subject matter accordingly. For example, the claims encompass a core containing a ring which is variously classified. The following is an illustration of the varied classification of the ring containing X, X1, X2, X3, and X4: If X, X1, X2, X3, and X4 are all carbon, the claims would be classified in class 564 and subclass 305+; if X and X1 are nitrogen, and X2, X3, and X4 are carbon, the claims would be classified in class 544 and subclass 238+; if X and X2 are nitrogen, and X1, X3, and X4 are carbon, the claims would be classified in class 544 and subclass 242+; if X and X3 are nitrogen, and X1, X2, and X4 are carbon, the claims would be classified in class 544 and subclass 336+; if X, X2, and X4 are nitrogen and X1, and X3 are carbon, the claims would be classified in class 544 and subclass 180+; etc. . . Thus, the requirement to restrict the claims in this application is predicated on the fact that the claimed subject matter involves more than one independent and distinct invention. Evidence of patentably distinct inventions is

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shown supra, in the variously classified ring containing X, X1, X2, X3, and X4. No where do Applicants point out and give reasons why the claims do not involve independent or distinct subject matter. Accordingly, the restriction is proper. Moreover, it would constitute a burden to extend the search because separate search considerations would be involved in both the U.S. Patents and in the literature. The examination process following the search could easily result in different and thus burdensome considerations.

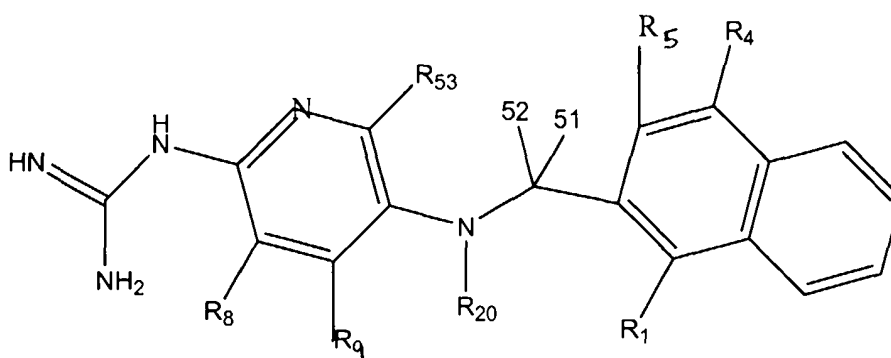
The restriction requirement here is predicated on the premise that the various compounds involved differ in structure and element so much so as to be patentably distinct, i.e. a reference which anticipated the elected compounds claimed would not even render obvious the others. Again, 35 U.S.C. 121 gives the Commissioner (Director) the authority to limit the examination of an application to a single invention. Applicants have not presented evidence that the examined subject matter is patentably indistinct from the non-examined subject matter. Nor have Applicants argued to the contrary. Moreover, the sheer number of variables, their huge possibilities, and the almost incomprehensible number of permutations and combinations thereof result in compounds so numerous and diverse so as to be a burden to classify, search, and examine. Accordingly, the requirement to restrict is considered proper and is maintained. The search and examination of the application is directed to the generic embodiment identified for examination only. (See below.)

Claims 1-31 are generic to a plurality of disclosed patentably distinct species comprising for example, the compounds of examples 150, 167, 174, etc. . . Therefore,

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it is necessary for a generic embodiment, inclusive of the elected species, to be carved out of generic claim 1. A search of Applicants' invention includes a search of patent literature in classes, and of patent and non-patent literature in computer databases. A severe burden would be imposed on the examination of this application if a generic embodiment were not carved out.

The generic embodiment is as depicted in claim 1, wherein the compound of Formula I is:



and R¹, R⁴, R⁵, R⁸, R⁹, R²⁰ and R⁵³ are as defined in claim 1, except that R⁴ and R⁵ cannot be taken together to form a ring, and R⁶ and R⁵³ cannot be taken together to form a ring because R⁶ is no longer a variable of formula 1; R² and R³ together form a ring (see the structure supra); and R⁵¹ and R⁵² taken together represent =O or =S. All of the above are identified for examination along with the elected embodiment. The remaining subject matter of claims 1-8 and 10-17 and the subject matter of claims 9 and 18-31 stands withdrawn from further consideration under 37 CFR 1.142(b) as constituting other patentably distinct inventions.

The withdrawn subject matter of claims 1-8 and 10-17 is properly restricted as said subject matter differs in structure and element from the elected subject matter so as to be patentably distinct therefrom, i.e. a reference which anticipated the elected subject matter would not even render obvious the withdrawn subject matter and fields of search are not co-extensive.

Claim Objections

Claims 1-8 and 10-17 are objected to as containing non-elected subject matter. This objection may be overcome by limiting the claims to the elected subject matter identified supra.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

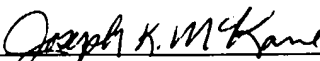
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the

applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.



Joseph K. McKane

Supervisory Patent Examiner

Group 1600

Sonya Wright

November 14, 2003